TMA DoD Pharmacoeconomic Center
Fort Sam Houston, TX

MTF Quarterly Webcast
June 13, 2013

Introduction

- Greetings from the PEC
- Purpose of the Quarterly MTF Webcast
- DCO Ground Rules
  - Type questions into the DCO system
  - Put on mute, not on hold
  - Contingency plan if DCO system stops working

Outline

- Review of February 2013 P&T Committee Meeting
- Follow-up from May 2012 P&T Committee Meeting – Smoking Cessation
- Overview of May 2013 P&T Committee Meeting
- Quick Look at August 2013 P&T Committee Meeting
- Questions

Review of February 2013 P&T Committee Meeting

Minutes available at:
http://pec.ha.osd.mil/pt_minutes.php?submenuheader=5

February 2013
DoD P&T Committee Meeting

- Uniform Formulary Class Reviews
  - Topical Pain Agents
  - Oral Anticoagulants

- New Drugs in Previously Reviewed Classes
  - Zolpidem Sublingual (Intermezzo)

Uniform Formulary Class Reviews

Topical Pain Agents

Drugs in Class

Generic Name	Brand (Manufacturer)	FDA Approval	Patent exp
Lidocaine 5% Patch	Lidoderm[a] (Endo Pharmaceuticals)	3/19/1999	5/2/2012*
Diclofenac epolamine 1.3% patch	Flector (Pfizer Pharmaceuticals)	1/31/2007	4/13/2014
Diclofenac sodium 1% gel	Voltaren (Endo Pharmaceuticals)	10/17/2007	10/17/2010**
Diclofenac sodium 1.5% solution + DMSO	Pennsaid (Covidien/Mallinckrodt)	11/04/2009	7/10/2029

[a]Lidoderm—orphan drug
*Generic launch anticipated 9/2013
** No generics on market

Overall Clinical Conclusion

- Topical lidocaine
  - Effective for postherpetic neuralgia (orphan indication)
  - Likely effective for other peripheral neuropathic pain conditions
  - Evidence lacking to support use for musculoskeletal pain or widespread pain
  - Minimal systemic absorption; side effects uncommon
  - Prescribed often for unsupportable conditions in MHS
    - Only 3% MHS Rxs for FDA-approved indication
  - High rate of discontinuation

- Topical diclofenac
  - Effective for superficial musculoskeletal pain (sprains/strains/osteoarthritis of superficial joints)
  - Highly interchangeable
  - Similar efficacy to oral diclofenac
  - Minimal systemic absorption; side effects are uncommon

Topical Pain Agents Final Decision

- Lidocaine 5% patch (Lidoderm), and diclofenac 1% gel (Voltaren) were designated Uniform Formulary
  - Lidoderm will require Prior Authorization (PA)

- Diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector) were designated Non Formulary

- No BCF agent in this subclass

Topical Pain Agents Lidoderm PA

- Prior Authorization
  - All users (new and current) need PA form
  - Only approved for
    - Post-herpetic neuralgia
    - Other types of peripheral neuropathic pain
    - Non-neuropathic pain where an occupational or clinical reason exists and other analgesics are contraindicated
  - Implementation date August 14
  - PA form will be found on TRICARE formulary search tool

Oral Anticoagulant Agents

Drugs in the Class

Generic Name	Brand name (Mfg)	Formulations	FDA Approval	Patent Expiration
Vitamin K Antagonists				
Warfarin (BCF since 1998)	Coumadin (BMS)	1, 2, 2.5, 3, 4, 5, 6, 7.5, 10 mg tabs	Jun 1954	-
Direct Thrombin Inhibitors				
Dabigatran	Pradaxa (BI)	75, 150 mg caps	Oct 2010	2018-2027
Factor Xa inhibitors				
Rivaroxaban	Xarelto (J&J)	10, 15, 20 mg tabs	Jun 2011	2020-2021
Apixaban*	Eliquis (Pfizer/BMS)	2.5, 5 mg tabs	Dec 2012	2019-2023

*Apixaban not reviewed due to lack of Federal pricing

Clinical Conclusion

- Newer oral anticoagulants (NOACs) have advantages of predictable anticoagulant effect, fixed dosing and fewer drug interactions compared to warfarin.
- Warfarin adverse effects are predictable and manageable.
- NOACs offer a convenience to patients; laboratory monitoring for efficacy and dietary restrictions are not required. More data is needed in patients with renal and hepatic impairment. No reversal agent is available with the NOACs.
- In non-valvular AFib, superiority to poorly controlled warfarin at preventing stroke was shown with dabigatran and apixaban, while non-inferiority was shown with rivaroxaban. Intracranial bleeding was lower with all 3 NOACs.
- Rivaroxaban has the most FDA indications of the NOACS: AFib, DVT/PE treatment, and VTE prophylaxis after hip/knee replacement surgery

Clinical Conclusion

- There is insufficient evidence due to a lack of head-to-head trials, to determine if one NOAC has advantages over the others.
- Patients require education and clinical monitoring to ensure appropriate use and avoid adverse reactions.
- It remains to be determined whether the NOACs will increase the numbers of patients currently undertreated for stroke prevention in Afib. NOACs. Also unknown is whether NOACs will improve persistence.

Oral Anticoagulants Final Decision

- Warfarin (Coumadin, generic) remains Basic Core Formulary
- Dabigatran (Pradaxa) & Rivaroxaban (Xarelto) designated Uniform Formulary

- Apixaban (Eliquis) will be reviewed as a new drug at an upcoming meeting

New Drugs in Previously Reviewed Classes

Zolpidem SL (Intermezzo)

Drugs in the Class

Active Ingredient	Brand (Manufacturer)	Strengths & Formulation	FDA Approval Date	Patent Expiration Date
Zolpidem IR	Ambien (generics)	5, 10mg tabs	12/16/1992	-
Zolpidem CR	Ambien CR (generics)	6.25, 12.5mg ER tabs	10/02/2005	-
Zolpidem Spray	Zolpimist (Novadel)	5mg/spray	12/19/2008	10/01/2017
Zolpidem SL Tab	Edluar (Meda)	5, 10mg sublingual tabs	03/13/2009	09/24/2019
Zolpidem SL Tab	Intermezzo (Purdue Pharma)	1.75, 3.5mg sublingual tabs	11/23/2011	2025
Eszopiclone	Lunesta (Sunovion)	1, 2, 3mg tabs	12/15/2004	02/14/2014
Zaleplon	Sonata (generics)	5, 10mg caps	08/13/1999	-
Ramelteon*	Rozerem (Takeda)	8mg tabs	07/22/2005	07/22/2019
Doxepin*	Silenor (Somaxon)	3, 6mg tabs	3/17/2010	2013-2020

* Not scheduled; everything else C-IV

Overall Clinical Conclusion

- Initial approaches to treatment of insomnia should include at least one behavioral intervention
- Intermezzo is the only low-dose sublingual oral formulation of zolpidem, available in 1.75mg and 3.5mg
- Intermezzo is indicated for the treatment of insomnia, characterized by middle-of-the-night (MOTN) waking followed by difficulty returning to sleep
- In one study, Intermezzo statistically decreased sleep latency and increased total sleep time more than placebo after MOTN awakening
- No studies have been completed with an active comparator
- Intermezzo should only be taken when a minimum of 4 hours of bedtime is remaining and should not be taken more than once per night
- Most commonly reported adverse reactions were headache, nausea and fatigue

Overall Clinical Conclusion

- Use caution when prescribing Intermezzo for patients taking CNS depressants, those being treated for depression, and patients with compromised respiratory function
- Intermezzo has a warning regarding severe allergic reactions and complex sleep-related behaviors
- Two open-label studies reported no serious adverse events or withdrawal symptoms
- Intermezzo is a C-IV product, along with zolpidem, eszopiclone, and zaleplon
- Despite it's unique FDA labeling compared to the other SED-1s, and the potential for less next-day impairment, Intermezzo does not offer a clinically compelling advantage over the other UF SED-1 drugs
- It is unknown whether taking ½ doses of the 5 mg zolpidem IR formulation would produce similar effects as Intermezzo

Intermezzo Final Decision

- Designated Non Formulary
  - Implementation July 17
- Prior Authorization Applies
  - Requires a trial of generic zolpidem IR or zaleplon

Utilization Management

Utilization Management

- Tretinoin
  - Age Restriction for Acne treatment lifted
  - Tretinoin products/derivatives specifically indicated for cosmetic use (e.g., Renova, Refissa, Avage) remain excluded from the pharmacy benefit

- Zolpidem Gender-Based Dosing
  - New FDA-labeling for dosing in women: 5 mg

Utilization Management

- Update to Quantity limits for
  - Aclidinium Inhaler (Tudorza)
  - Beclomethasone dipropionate nasal inhaler (Qnasl)
  - Ponatinib (Inclusig)
  - Cabozantinib (Cometriq)

Follow-up From May 2012 P&T Committee Meeting – Smoking Cessation Program

Smoking Cessation Background

- Change in Federal Law (2009 NDAA) allows smoking cessation drugs (Rx and OTC products) at MTF and Mail Order in select beneficiary groups (>18 yrs; non-Medicare eligible)

- The program is intended to expand access to treatment for nicotine dependent beneficiaries.

- May 2012 P&T Committee identified which prescription and OTC products would be included or excluded from the Smoking Cessation “Program”

- Feb 27 2013TRICARE Final Rule published with an effective date of 29 Mar 2013.
  - https://www.federalregister.gov/articles/2013/02/27/2013-03417/tricare-smoking-cessation-program

Smoking Cessation Program – Final Decisions

- BCF products
  - OTC Nicotine Transdermal System 7-, 14-, 21mg
    - National Contract with Novartis and GSK
  - OTC Nicotine gum 2mg, 4 mg
  - Bupropion SR 150

  - *OTC products require a prescription

- Uniform Formulary
  - Varenicline (Chantix)
  - Nicotine lozenge
  - Nicotine inhaler (Nicotrol)
  - Nicotine nasal spray (Nicotrol NS)

Smoking Cessation Key Points

- BCF products should be available to eligible beneficiaries.

- MTF Smoking Cessation Programs
  - Local MTFs remain at liberty to design their own smoking cessation program, defining which elements will be included in that program.

- Quit Attempts
  - Rule allows for 2 quit attempts, defined as 120-day periods, available annually
  - 3rd attempt in one year allowed with prior authorization
    - Provider must document that patient will benefit from a 3rd attempt

- Gum and lozenge quantity limits
    - 600 pieces per 60 days/Rx claim – rounded to nearest multiple of package size (e.g., boxes of 75 or 100)

Overview of May 2013 P&T Committee Meeting

May 2013 DoD P&T Committee Meeting

- Uniform Formulary Class Reviews
  - Gout
  - COPD
- New Drugs in Previously Reviewed Classes
  - Canagloflozin (Invokana)
    - New SGLT2 inhibitor; new sub-class of Non-insulin Diabetes drugs
- BCF Clarifications
  - Mesalamine delayed release (Asacol)
  - Next Choice (emergency contraception)

Quick Look at August 2013 P&T Committee Meeting

August 2013
DoD P&T Committee Meeting

- Uniform Formulary Class Reviews
  - Topical Steroids – Cost Review & Formulary Decisions
  - Self Monitoring Blood Glucose Strips- Cost Review & Formulary Decisions
  - Angiotensin II Receptor Blockers - Full Review

- New Drugs
  - Alogliptin, with metformin, with pioglitazone
    - DPP-4 inhibitor; sub-class of Non-insulin Diabetes drugs

Miscellaneous items

- New PEC website
  - Let us know if you find something that doesn't look right
- PECUF Email address are being updated
  - More to come on new email address
- Next webcast: September 12, 2013

Webcast Evaluations

- Please assist us in improving the webcast presentations by completing an anonymous, 5-question survey
- Link: http://www.zoomerang.com/Survey/WEB22CTVSNWFRP
- Thank you!

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  - PECUF Address was dropped in transition
    - Working on technical solution

Questions?